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Diagnostic article

[0001] The present application hereby claims priority under 35 U.S.C. §119 on German patent application number DE 103 05 831.1 filed February 12, 2003, the entire contents of which are hereby incorporated herein by reference.

Field of the Invention

[0002] The invention generally relates to a diagnostic article. In particular it relates to one for medical applications, preferably including a microneedle array.

Background of the Invention

[0003] A diagnostic article is known, for example, from US 6,379,324 B1.

[0004] A microneedle array is known from WO 02/17985 A2, for example. This microneedle array is produced by etching processes and has individual hollow needles with an internal diameter of typically 20 µm and a length of typically 0.5 mm. Such a microneedle array is intended to transport a fluid through a dermal barrier in medical applications. For example, a medicament can be administered in this way, or a blood sample collected. The advantage of the microneedle array is intended in particular to be that it is painless to use.

[0005] The microneedle array known from US 6,379,324 is part of what is called a closed-loop system. In this case, different microneedle arrays are used for collecting samples, for delivering medication, and also as an electrode arrangement. Further, both hollow and solid microneedles are employed.

[0006] A further medical application of microneedle arrays is known from WO 02/091922. A so-called microneedle strip includes, in addition to the microneedle array, a fluid channel and a diaphragm pump.

SUMMARY OF THE INVENTION

[0007] An object of an embodiment of the invention is to make available a diagnostic article which exploits the properties of a microneedle array in a particularly advantageous manner.

[0008] According to an embodiment of the invention, an object may be achieved by a diagnostic article. This diagnostic article may include a microneedle array which is supported by a holding device, namely a so-called diagnostic glove, or is an integral part of such a holding device. The holding device does not necessarily have to have five fingers or a closed form. In any event, the holding device can be worn in a simple and comfortable manner by the user.

[0009] The microneedle array is preferably designed as a disposable component which is discarded after each analysis. The microneedles are able to take up a fluid, for example blood, and forward it, for example by capillary forces, when the microneedle array is pressed onto the sample. Only very small sample volumes are needed here.

[0010] Integrated in the microneedle array and/or the holding device there is a fluid system with which the sample can be prepared, derivatized, and delivered to a detection unit likewise integrated in the microneedle array and/or in the holding device, which detection unit permits a measurement. The measurement results

obtained in this way are processed and stored in a data evaluation device, or so-called data module, which is connected to the detection unit also designated as data recording device, and/or are conveyed for storage from the data module to an additional module or a higher-ranking data system. The data module can be an integral part of the holding device designed as diagnostic glove, or can be connected mechanically to the holding device, or can be a part of the diagnostic article withdrawn from the holding device.

[0011] A display device on the holding device is also connected to the data module. The holding device may be designed as one piece, and support both the microneedle field and the display device. Alternatively, it can be designed in a number of pieces. As such, a first part can include the microneedle array, and a second part can be connected, not necessarily mechanically, to the first part and can include the display device. In any event, the display device can, like the microneedle array, be easily worn by the user, for example on the hand.

[0012] According to a particularly advantageous development, the data module can be connected by a data link to a dosing unit. When an examination, in particular a blood examination, of a patient is performed by use of the microneedle array, the dosing unit allows a medicament to be administered to the patient in a precisely dosed quantity. This occurs as a function of the test results obtained with the aid of the microneedle array. In this way, a closed-loop system is produced.

[0013] The diagnostic article is particularly suitable for association with an electronic patient record. The electronic patient record can in this case be stored in

the diagnostic article itself, particularly in the data module. Alternatively, a data link can simply be provided to an electronic patient record managed in an external system. This permits an immediate or at least almost contemporaneous comparison of the data obtained with the diagnostic article and the data stored in the electronic patient record.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The present invention will become more fully understood from the detailed description of preferred embodiments given hereinbelow and the accompanying drawings, which are given by way of illustration only and thus are not limitative of the present invention.

[0015] An illustrative embodiment of the invention is explained in more detail below with reference to diagrammatic figures, wherein:

Fig. 1	shows a diagnostic article with a microneedle array, a data module, and a display device,
Figs 2 and 3	show details of the diagnostic article according to Fig. 1, and
Fig. 4	shows a cross section through a microneedle of the diagnostic article according to Fig. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] Fig. 1 shows a diagnostic article 1 with a diagnostic and analysis glove, referred to in short as

a diagnostic glove, generally designated as holding device 2. A microneedle array 3 is secured on at least one finger of the diagnostic glove 2. The microneedle array 3 has a multiplicity of microneedles 4 which, as can be seen from Fig. 2 and in particular from Fig. 3, are directed outward.

[0017] In the illustrative embodiment shown, the diagnostic glove 2 is thus not intended for examining blood from the person wearing the diagnostic glove 2. Rather, with a microneedle array 3 arranged for example on the tip of the thumb and on the tip of the index finger of the diagnostic glove 2, a blood sample can be collected from a suitably perfused part of the body of a patient or animal. However, the diagnostic glove 2 can also be used, for example, to examine a transplant organ or a food specimen, for example a piece of meat or cheese. According to an alternative embodiment, the microneedles 4 in the diagnostic glove 2 are directed inward, so that the blood of the person wearing the diagnostic glove 2 can be examined.

[0018] An individual microneedle 4 shown in cross section in Fig. 4 has a height H of not more than 2 mm, in particular not more than 0.5 mm. A fluid channel 5 within the microneedle 4 has a diameter d of approximately 20 µm to 150 µm. A multiplicity of microneedles 4 are arranged in a matrix formation within the microneedle array 3.

[0019] The geometry of the microneedles 4 makes it possible to take blood from a patient or to deliver medicaments through the dermal barrier practically without pain. The microneedles 4 are designed to convey a collected sample, in particular a blood sample, through the fluid channel 5 to a detection article 6 which, in the illustrative embodiment, is designed

integrally with the microneedle array 3 and with this forms an analysis chip.

[0020] The detection article 6, also designated as data recording device, is connected via a data link, indicated by a broken line in Fig. 1, to a data module 7 also designated as data evaluation device. In the illustrative embodiment, the data module 7 is arranged outside the holding device 2. However, it can also be integrated into the holding device 2 or into the detection article 6. The data link between the detection article 6 and the data module 7 can be produced, for example, by way of a cable or by way of a wireless connection, for example a radio connection.

[0021] In cases where data have been determined on examining a patient, the data module 7 serves to transmit the data obtained with the aid of the microneedle array 3 to an electronic patient record EPR. The electronic patient record EPR can either be stored in the data module 7, as indicated in Fig. 1, or in a higher-ranking data system to which the data module 7 is linked. The data module 7 can likewise be realized in software form in a data processing system.

[0022] The data processed in the data module 7 and derived from the measurements carried out with the aid of the microneedle array 3 are compared with the data present in the electronic patient record EPR, in particular the individual data concerning the patient. The result of this measurement can, for example, trigger a follow-up measurement, either again via the microneedle array 3 or via another system not shown.

[0023] To display data obtained with the aid of the data module 7, a display module 8 connected to it is provided on the holding device 2. The display module or

the display device 8 allows the user, for example a physician, to view the results of the measurements carried out with the aid of the microneedle array 3 and to do so practically in real time. In the illustrative embodiment, the holding device 2 for securing the microneedle array 3 is identical to the one for receiving the display module 8, that is to say designed as a glove, in this case with the display module 8 arranged on the back of the glove. In alternative embodiments, the holding device 2 is designed in a number of parts.

[0024] In addition to the display of data generated in the data module 7, there is also a link between the data module 7 and a dosing unit 9. The data link, which can be realized in any desired manner, for example as a radio link in a network within which data from the electronic patient record EPR are also transmitted, is symbolized in Fig. 1 as a broken line, like the other data links mentioned above. The dosing unit 9 serves to administer a medicament to the patient as a function of the measurement results evaluated in the data module 7, and taking into account the electronic patient record EPR. The microneedle array 3 for collecting the sample is coupled to the dosing unit 9 to form a closed-loop system.

[0025] Because the microneedle array 3 is easy to handle, the diagnostic article 1 is also particularly suitable for self-testing, for example in the case of diabetes patients, as so-called monitoring device. By using the diagnostic article 1, the diagnosis is personalized, as the direct personal contact is part of the diagnosis process. The display module 8 integrated in the holding device 2 or supported by it additionally permits rapid reaction to the measurement result obtained with the aid of the microneedle array 3.

[0026] Exemplary embodiments being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the present invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.